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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,972	03/22/2004	Stephen Donovan	17500CON (BOT)	2337

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STEPHEN DONOVAN
ALLERGAN, INC.
T2-7H
2525 Dupont Drive
Irvine, CA 92612

EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/806,972	DONOVAN, STEPHEN	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-22 have been amended and are under consideration.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 8, 2005 has been entered.

2. The Amendment submitted After Final has been entered and will be considered in a non-final office action set forth herein.

Response to Arguments

1. Applicant's arguments with respect to claims 1-22 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

4. All of the claims have been amended to recite the phrase "administered to a site of the brain located within the skull of the patient". The examiner upon reconsideration of the disclosure of the instant Specification, could not find original descriptive support for this phrase. Nor was the scope of this phrase found to be defined in the instant Specification.

5. The examiner upon consideration of Applicant's Exhibit A, Exhibit A having been submitted in support of the newly submitted combination of claim limitations, defines the phrase "skull base" . The examiner upon further reconsideration of the instant Specification, also could not find the term "skull base" in the instant Specification.

6. While the instant Specification does provide original descriptive support for the term "intracranial". The Glossary of Skeletal Anatomy defines the term "cranium" to include the face and the calvarium"; and the term "calvarium" includes the brain case. Therefore the term "intracranial" defines those parts of the head that include the face and the brain case. The term "skull" includes the cranium and the mandible parts of the head and is therefore broader in meaning than the term "intracranial". The definition of cranium does not include the mandible lower jaw portion of the head which the term skull includes within its meaning. Therefore the term skull and the term intracranial do not have the same definition, and though related terms, do not evidence one in the same meaning.

Applicant's traversal asserts the phrase "a site of the brain within the skull" appears to define the site to not be a site within the boney region of the brain case (calvarium), or within the patients face (intracranial: face and calvarium) but to include the "lower brain regions and the pontine region". Emphasis has been placed on reading the phrase "locally administered to a site of the brain within the skull of the patient" to define the invention to be brain regions that are

surrounded by the boney brain case, rather than locally to an intracranial site. Clearly, the term intracranial does not provide original descriptive support for the local administration of botulinum toxin to any region of the brain that is surrounded by the boney brain case as well as within the boney case of the skull. This scope of the invention could not be found in the instant Specification which was directed to local administration to an intracranial site which included the face of a patient, and Applicant's traversal is based upon a newly submitted combination of claim limitations that excludes the face, the face being a part of the definition of cranium, and the face being a local site of an intracranial region of the head.

Therefore, all of the claims recite New Matter, in light of the claims having been amended to recite the phrase "locally administered to a site of the brain within the skull of a patient" which does not evidence original descriptive support in the instant Specification . Amendment of claim 8 into independent form and removal of the phrase "locally administered to a site of the brain within the skull of a patient", could possibly obviate this rejection over claims 8-9. Amendment of claim 1 to recite the combination of claim limitations previously recited, specifically, "intracranial site", could obviate this rejection.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-7, 10-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,921,538. Although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed species which administers the botulinum toxin to a patient to alleviate a symptom of a neuropsychiatric disorder administers the composition to an intracranial site, which is a species of location within the scope of the genus term "skull" which includes both the cranium and mandible by definition. Therefore, the allowed species anticipates the instantly claimed genus of methods of alleviating symptoms of a neurophsychiatric disorder

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-7, 10-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Aoki et al (US Pat. 6,113,915).

5. Aoki et al claim a method of treating pain, the method comprising the step of :

administering a botulinum toxin to a cranial region (see Aoki et al, claim 13 and col. 20, claims 1-13, 29), a local site of administration to a site of the brain within the skull of the patient,

wherein the cranial region of the central nervous system is administered botulinum toxin to alleviate at least one symptom of pain, the alleviated symptom resulting in improved patient function, reduced pain, reduced time spent in bed, increased ambulation, healthier attitude and a more varied lifestyle (see Aoki et al, col. 8 lines 57-60).

The patients to which the botulinum toxin is administered evidence at least one symptom of a neuropsychiatric disorder, the reference treating patients with neuropathic pain that is from a persistent or chronic pain syndrome that can result from neuropathic pain syndromes or disorders that include allodynia, various neuralgias such as post herpetic neuralgia and trigeminal neuralgia, phantom pain, and complex regional pain syndromes, such as reflex sympathetic dystrophy and causalgia characterized by spontaneous burning pain combined with hyperalgesia and allodynia.

Aoki et al anticipates the instantly claimed invention as now claimed.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

7. Weinberger et al (US Pat. .5549884) is cited to show a method that administers a neurotoxin to the brain of a rat or mouse (hippocampus) and is non-lethal.

8. Gillies et al (US pat. 6,272,370) is cited to show the administration of a neurotoxin to the skull of an Alzheimer's patient (see col. 13, line 30 "intracranial drug delivery"; col. 24, line 5 "Alzheimer's disease"; see Figure 1; col. 11, lines 4-5, 22-25; claim 31).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
September 25, 2005

L. R. F. Smith
LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600